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10/780,211	02/17/2004	Rainer Kuth	P03,0622	9905

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EXAMINER	
SEREBOFF, NEAL	
ART UNIT	PAPER NUMBER
3626	

MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/780,211	KUTH ET AL.	
	Examiner	Art Unit	
	NEAL R. SEREBOFF	3626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 October 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2-10 and 12* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2-10 and 12* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

1. In the Amendment dated 10/22/2008, the following has occurred: Claims 2 - 4, 7 10 and 12 have been amended; Claims 1 and 11 have been previously canceled. Claims 2 – 10 and 12 are pending.

Notice to Applicant

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. Claims 2 – 10 depend upon claim 12. For clarity, the rejection below of claim 12 precedes the rejections below of claims 2 - 10.

4. Within the remarks dated 5/7/2008, the Applicant did not challenge that a clinical trial administrator and the research entity commissioning the study can be the same. The Examiner notes that it is now Applicant Admitted Prior Art (AAPA) that a clinical trial administrator and the research entity commissioning the study can be the same. In the remarks dated 10/22/2008, the Applicant requested the statutory basis for the statement above.

The Examiner refers the Applicant to MPEP §2144.03 (c):

> If applicant does not traverse the examiner's assertion of official notice or applicant's traverse is not adequate, the examiner should clearly indicate in the next Office action that the common knowledge or well-known in the art statement is taken to be admitted prior art because applicant either failed to traverse the examiner's assertion of official notice or that the traverse was inadequate. If the traverse was inadequate, the examiner should include an explanation as to why it was inadequate.

Claim Rejections - 35 USC § 101

5. Claims 2 - 10 and 12 are rejected under 35 U.S.C. 101 based on Supreme Court precedent, and recent Federal Circuit decisions, a § 101 process must (1) be tied to a machine or (2) transform underlying subject matter (such as an article or materials) to a different state or thing. Diamond v. Diehr, 450 U.S. 175, 184 (1981); Parker v. Flook, 437 U.S. 584, 588 n.9 (1978); Gottschalk v. Benson, 409 U.S. 63, 70 (1972); Cochrane v. Deener, 94 U.S. 780,787-88 (1876). The process steps in claims (2 - 10 and 12) are not tied to a machine nor do they execute a transformation. Thus, they are non-statutory.

Claim Rejections - 35 USC § 112

6. Claims 2 – 10 and 12 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 12 introduces new that, "generating a customized input platform program that includes a collection of input fields configured only and precisely for entry of the data that is necessary for the specific medical study." The Examiner interprets "only and precisely" to modify the configuration of the input fields for data entry, or specifically how the data is being entered.

The Pre-Grant Publication paragraph 13 states:

This method ensures that, in a clinical study, identical input platforms are generated at all participating input locations, via which only such data can be input that are required for precisely this clinical study and that are incurred at the current input location in the examination of the study participant. The type of the data input and data storage is always the same, not only within an individual clinic, but rather also for a plurality of participating clinics. Even when the input locations are spatially separated by a great distance and are organized very differently, a uniform and complete recording, and thus also a simple evaluation of the study data, is therewith possible.

Therefore, the Examiner understands that the displayed field labels are the same. The specification does not define "type of the data" and therefore the Examiner understands that the "type of the data" is text. Claims 2 – 10 are rejected for the same reason as they depend upon claim 12.

7. Claims 2 – 10 and 12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The term "only and precisely" in claim 12 is a relative term which renders the claim indefinite. The term "only and precisely" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Claims 2 – 10 are rejected for the same reason as they depend upon claim 12.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claim 12 is rejected under 35 U.S.C. 102(b) as being anticipated by Official Notice.

10. As per claim 12, the Examiner takes Official Notice that a method to input and store data for a medical clinical study, comprising the steps of:

- Generating a customized input platform program that includes a collection of input fields configured only and precisely for entry of the data that is necessary for a specific medical clinical study;
- Distributing said customized input platform program to each of a plurality of input locations that respectively interface with patients participating in the specific medical clinical study;
- Upon interfacing at one of said input locations with one of said patients, entering a characteristic identifying that patient into a computer system at the input location and, via the computer system, automatically calling and activating said customized input platform program solely for said specific medical clinical study by entry of said characteristic;
- At said input location, providing data for said specific medical clinical study only by making entries in the respective data fields of the unique customized input platform program presented at the computer at the input location; and
- Storing the data entered via the customized input platform program generate a database for said customized input platform program and making said database available to participants in said specific medical clinical study.

Although the Applicant's intent may be otherwise, the Examiner takes Official Notice that the Applicant has claimed a method of using a piece of paper. The nominal use of the computer above may only be for accessing a room where the sheet of paper is stored. The storage of that paper within a filing cabinet would anticipate the database limitation.

11. ***Claims 12 and 9*** are rejected under 35 U.S.C. 102(e) as being anticipated by Tkaczyk et al., U.S. Pre-Grant Publication Number 2004/ 0059597.

12. As per claim 12, Tkaczyk, as understood, teaches a method to input and store data for a medical clinical study, comprising the steps of:

- Generating a customized input platform program that includes a collection of input fields configured only and precisely for entry of the data that is necessary for a specific medical clinical study (paragraphs 26 and 35 – 48 where the template is used and other fields are automatically filled and further that the claimed data required is non-functional and therefore not limiting. Further the intended use of the fields does not have patentable weight.);
- Distributing said customized input platform program to each of a plurality of input locations that respectively interface with patients participating in the specific medical clinical study (paragraph 37 where the information is presented on a web page. The use of patients is non-functional descriptive information in that replacing patient with user does not change the method result);
- Upon interfacing at one of said input locations with one of said patients (figure 2, #14 and paragraph 30), entering a characteristic identifying that patient into a computer system at the input location and (paragraphs 38, 39 and 41, access where the patient label is non-functional), via the computer system (figure 2), automatically calling and activating said customized input platform program solely for said specific medical clinical study by entry of said characteristic (paragraph 42 where the options are limited to what is available);

- At said input location, providing data for said specific medical clinical study only by making entries in the respective data fields of the customized input platform program presented at the computer at the input location (The Examiner is not sure who is providing the data and what data is being provided. The Examiner understands this limitation to be that the 'user enters text into fields.' paragraph 33 where the data is non-functional descriptive information and therefore has no patentable weight. The entered data is non-functional as no processing steps are performed on the data.); and
- Storing the data entered via the customized input platform program to generate a database for said customized input platform program and making said database available to participants in said medical clinical study (paragraph 33).

13. As per claim 9, Tkaczyk teaches the method of claim 12 as described above. Tkaczyk further teaches the method comprising, via said input platform, permitting only inputs that are required for said specific medical clinical study and that are incurred at the input locations that interface with patients participating in the specific medical clinical study (paragraph 26 where the fields are created to prompt a user to enter study information).

Claim Rejections - 35 USC § 103

14. ***Claim 2 – 8*** are rejected under 35 U.S.C. 103(a) as being anticipated by Tkaczyk et al., U.S. Pre-Grant Publication Number 2004/ 0059597 in view of Teshima, U.S. Patent Number 6,272,470.

15. As per claim 2 Tkaczyk teaches the method of claim 12 as described above.

Tkaczyk does not explicitly teach the method comprising distributing the customized input platform program in a framework of a medical data standard.

However, Teshima further teaches the method comprising distributing the customized input platform program in a framework of a medical data standard (column 1, lines 53 – 67 where the standard is DICOM where the platform is customized by adding the DICOM standard).

It would have been obvious to one of ordinary skill in the art at the time of the invention to add this feature into Tkaczyk. One of ordinary skill would have added this feature into Tkaczyk with the motivation to solve the problem of the storage capacity of a portable storage unit, and to provide an electronic clinical recording system for a wide-area hospital information system enabling the whole of a region to share medical information at low cost without any concern about a difference in type of equipment or 0S (Teshima, column 3, lines 8 – 15).

16. As per claim 3, Tkaczyk teaches the method of claim 12 as described above.

Tkaczyk does not explicitly teach the method comprising storing the customized input platform program in a region of the medical data standard reserved for patient data.

However, Teshima further teaches the method comprising storing the customized input platform program in a region of the medical data standard reserved for patient data (column 3, lines 8 – 67 where the system is customized to operate on a portable input platform).

It would have been obvious to one of ordinary skill in the art at the time of the invention to add this feature into Tkaczyk. One of ordinary skill would have added this feature into Tkaczyk with the motivation to solve the problem of the storage capacity of a portable

storage unit, and to provide an electronic clinical recording system for a wide-area hospital information system enabling the whole of a region to share medical information at low cost without any concern about a difference in type of equipment or 0S (Teshima, column 3, lines 8 – 15).

17. As per claim 4, Tkaczyk teaches the method of claim 12 as described above.

Tkaczyk does not explicitly teach the method comprising storing the data acquired at an input location ensues in a data format that is determined by the customized input platform program.

However, Teshima further teaches the method comprising storing the data acquired at an input location ensues in a data format that is determined by the customized input platform program (column 14, lines 26 – 67 where system is customized to allow for different displays).

It would have been obvious to one of ordinary skill in the art at the time of the invention to add this feature into Tkaczyk. One of ordinary skill would have added this feature into Tkaczyk with the motivation to solve the problem of the storage capacity of a portable storage unit, and to provide an electronic clinical recording system for a wide-area hospital information system enabling the whole of a region to share medical information at low cost without any concern about a difference in type of equipment or 0S (Teshima, column 3, lines 8 – 15).

18. As per claim 5, Tkaczyk in view of Teshima teaches the method of claim 4 as described above.

Tkaczyk does not explicitly teach the method comprising storing the acquired data in a framework of a medical data standard.

However, Teshima further teaches the method comprising storing the acquired data in a framework of a medical data standard (column 14, lines 26 – 34 where the standard is DICOM).

It would have been obvious to one of ordinary skill in the art at the time of the invention to add this feature into Tkaczyk. One of ordinary skill would have added this feature into Tkaczyk with the motivation to solve the problem of the storage capacity of a portable storage unit, and to provide an electronic clinical recording system for a wide-area hospital information system enabling the whole of a region to share medical information at low cost without any concern about a difference in type of equipment or 0S (Teshima, column 3, lines 8 – 15).

19. As per claim 6, Tkaczyk in view of Teshima teaches the method of claim 4 as described above.

Tkaczyk does not explicitly teach the method comprising storing the acquired data in a region of the medical data standard reserved for patient data.

However, Teshima further teaches the method comprising storing the acquired data in a region of the medical data standard reserved for patient data (column 11, lines 8 – 45 where the patient card contains patient data).

It would have been obvious to one of ordinary skill in the art at the time of the invention to add this feature into Tkaczyk. One of ordinary skill would have added this feature into Tkaczyk with the motivation to solve the problem of the storage capacity of a portable storage unit, and to provide an electronic clinical recording system for a wide-area hospital information system enabling the whole of a region to share medical information

at low cost without any concern about a difference in type of equipment or 0S (Teshima, column 3, lines 8 – 15).

20. As per claim 7, Tkaczyk in view of Teshima teaches the method of claim 2 as described above.

Tkaczyk does not explicitly teach the method comprising using the Digital Imaging and Communication in Medicine (DlCOM) standard as the medical data standard.

However, Teshima further teaches the method comprising using the Digital Imaging and Communication in Medicine (DlCOM) standard as the medical data standard (column 14, lines 26 – 34).

It would have been obvious to one of ordinary skill in the art at the time of the invention to add this feature into Tkaczyk. One of ordinary skill would have added this feature into Tkaczyk with the motivation to solve the problem of the storage capacity of a portable storage unit, and to provide an electronic clinical recording system for a wide-area hospital information system enabling the whole of a region to share medical information at low cost without any concern about a difference in type of equipment or 0S (Teshima, column 3, lines 8 – 15).

21. As per claim 8, Tkaczyk in view of Teshima teaches the method of claim 4 as described above.

Tkaczyk does not explicitly teach the method comprising distributing the customized input platform program in a framework of a medical data standard that is the Digital Imaging and Communication in Medicine (DlCOM) standard.

However, Teshima further teaches the method comprising distributing the customized input platform program in a framework of a medical data standard that is the Digital Imaging and Communication in Medicine (DlCOM) standard (column 14, lines 26 – 34). It would have been obvious to one of ordinary skill in the art at the time of the invention to add this feature into Tkaczyk. One of ordinary skill would have added this feature into Tkaczyk with the motivation to solve the problem of the storage capacity of a portable storage unit, and to provide an electronic clinical recording system for a wide-area hospital information system enabling the whole of a region to share medical information at low cost without any concern about a difference in type of equipment or 0S (Teshima, column 3, lines 8 – 15).

22. ***Claim 10*** is rejected under 35 U.S.C. 103(a) as being anticipated by Tkaczyk et al., U.S. Pre-Grant Publication Number 2004/ 0059597 in view of Thangaraj et al., U.S. Pre-Grant Publication Number 2003/ 02008378.

23. As per claim 10, Tkaczyk teaches the method of claim 12 as described above. Tkaczyk does not explicitly teach the method comprising generating the customized input platform program by a research entity commissioning the specific medical study. However, Thangaraj teaches the method comprising generating the input platform by a research entity commissioning the specific medical study (paragraph 75 where the administrator sets up user functionality and paragraphs 82 and 83 that state that the clinical trial administrator is the same as the system administrator).

A clinical trial administrator and the research entity commissioning the study can be the same. The Examiner therefore interprets the claim through this understanding (AAPA).

It would have been obvious to one of ordinary skill in the art at the time of the invention to add this feature into Tkaczyk.

- One of ordinary skill in the art would have added this feature into Tkaczyk with the motivation to create an Internet-based solution to clinical trial management (Thangaraj paragraph 5).
- The technical ability existed to add the Thangaraj feature into Tkaczyk as claimed and the substitution result is predictable.

Response to Arguments

24. Applicant's arguments, see 35 U.S.C. 112 1st paragraph, filed 10/22/2008, with respect to claims 2 – 10 and 12 have been fully considered and are persuasive. The 35 U.S.C. 112 1st paragraph rejection of claim 2 – 10 and 12 have been withdrawn.

25. Applicant's arguments, see 35 U.S.C. 112 2nd paragraph, filed 10/22/2008, with respect to claims 2 – 10 and 12 have been fully considered and are persuasive. The 35 U.S.C. 112 2nd paragraph rejection of claim 2 – 10 and 12 have been withdrawn.

26. Regarding the Applicant's desire to be his own lexicographer, the Examiner agrees with that assertion. However, in the process of creating customized definitions, the Applicant may not add new matter. Please see the above 35 U.S.C. 112 1st rejection.

27. The Applicant commented upon the Examiner's suggestions as detailed below:

- The Examiner notes that the claimed method is similar to creating a web page based upon template material. That web page could also be an informed consent form as described in Califano et al., U.S. Pre-Grant Publication 2003/ 0033168. The Examiner notes that this reference, although not currently applied, anticipates

claim 12. Any potential future amendments should be made with regard to Califano also anticipating claim 12.

- In general, dynamically creating web based forms based upon user input is old and well known and multiple examples of this exist within prior art. Further, limiting access to forms is old and well known and multiple examples exist within the prior art. Even if these examples were not specifically for a medical study, the Examiner would find ample reasons to make these combinations. The Examiner suggests that the Applicant further consider potential future amendments in view of recent US Supreme Court decisions and Court of Appeals for the Federal Circuit decisions.
- The Examiner understands that this is not a formal rejection, however it is in the Applicant's best interest to further prosecution. The Examiner made these suggestions in hopes that the Applicant would consider this art, although not applied, and make additional amendments. These secondary amendments would have potentially moved the Application further without additional rounds of prosecution.
- Additionally, the MPEP does not require the Examiner to explicitly match prior art toward the claim limitations. See example of the 35 U.S.C. 102(b) rejection above.

28. Applicant's arguments filed 10/22/2008 have been fully considered but they are not persuasive.

- Regarding the Applicant Admitted Prior Art - Please see the additional comments above

- Regarding the 35 U.S.C. 101 rejection
    - The Applicant quotes MPEP 2107.3 regarding a tangible result. The Examiner believes that the Applicant quoted the incorrect MPEP section because 2107.03 is titled, "Special Considerations for Asserted Therapeutic or Pharmacological Utilities."
    - MPEP 2106 is titled "Paten Subject Matter Eligibility" and 2106(IV) regards "Determine Whether the Claimed Invention complies with 35 U.S.C. 101"
        - The test is multi-step with the last step being, "C. Determine Whether the Claimed Invention Falls Within 35 U.S.C. 101 Judicial Exceptions – Laws of Nature, Natural Phenomena and Abstract Ideas." This section is where the idea of "tangible result" is found.
        - However, the last item in section A describes the idea that "one may not patent every 'substantial practical application' of an idea, law of nature or natural phenomena." For the instant application, the Examiner made that pre-emption rejection. This 35 U.S.C. 101 rejection was backed up by the recent court decision, in re Bilski, — F.3d —, 88 U.S.P.Q.2d 1385 (2008).

29. Applicant's arguments fail to comply with 37 CFR 1.111(b) because they amount to a general allegation that the claims define a patentable invention without specifically pointing out how the language of the claims patentably distinguishes them from the references.

30. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.,* 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Conclusion

31. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NEAL R. SEREBOFF whose telephone number is (571)270-1373. The examiner can normally be reached on Mon thru Thur from 7:30am to 5pm, with 1st Fri off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Luke Gilligan can be reached on (571) 272-6770. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/N. R. S./
Examiner, Art Unit 3626
12/10/2008

/C Luke Gilligan/
Supervisory Patent Examiner, Art Unit 3626